

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Marc Howard Spinoza

Serial No.: 09/506,361

Filed: February 18, 2000

For: A METHOD OF SECURING A LINE TO
A PATIENT, FASTENERS AND THEIR
USE TO SECURE A LINE TO A
PATIENT

Group Art Unit: 3763

Examiner: VU, Quynh-Nhu Hoang

Atty. Dkt. No.: FIFW:019US

DECLARATION OF MARTIN JOHN ELLIOTT UNDER 37 C.F.R. § 1.132

I, Martin John Elliott, declare that:

1. I do not have a financial interest in the issuance of the above-captioned patent application.
2. Dr. Spinoza has sent me a copy of the above-captioned patent application. I have reviewed the application. I have reviewed the claims that I am told are being submitted in response to an Office Action dated November 29, 2007. I have also seen a prototype device of Dr. Spinoza's invention.
3. I am Chief of Cardiothoracic Surgery and Transplantation at the Great Ormond Street Hospital for Children NHS Trust, London WC1 N 3JH
4. I am a Medical Practitioner qualifying in 1973 as MBBS, receiving the academic qualification of MD (Doctorate at Medicine, similar to an American PhD) in 1983, and becoming a fellow of the Royal College of Surgeons in 1978. I trained as a General Surgeon, an adult Cardiac Surgeon, and finally as a Pediatric Cardiac Surgeon and am now a Consultant Pediatric Cardiothoracic Surgeon at the Great Ormond Street Hospital for Children, London. I have been

practicing there as a Consultant (attending) since 1985 and am now Chief of Cardiothoracic Surgery and Transplantation.

5. To date I have published 145 peer reviewed papers, 20 invited articles, 3 books and 27 chapters in books. I have given 246 invited lectures of which 10 have been plenary lectures. These have been delivered at centers and meetings throughout the world.

6. I am considered by others as an expert in cardiopulmonary bypass, pediatric thoracic surgery and the surgery for congenital heart defects, in addition to transplantation. I have been working in the field of cardiothoracic surgery including in children since 1978,

7. My impressions are that this is a simple, elegant, and clever idea and design, which will have widespread applicability in my field. Its versatility means that, once established, it should be applicable in numerable circumstances in which tubes or cables can be fixed to, e.g., child's skin, resulting in minimal trauma and great safety, a key element in the design of such a product.

8. Current practice of the insertion of, e.g., chest drains into a child is that a hole is first made in the body and the chest drain inserted, and then in order to fix the chest drain to the skin to stop it moving, a suture is first passed through the skin and then wrapped around the plastic tube of the drain to hold it in place. This is inherently difficult, the drain is prone to movement, the stitch is prone to fracture, and the forces exerted on the suture are very localized, making it possible to damage the drain. To prevent movement of the drain in the skin and out of the child, the drain is frequently taped to the side of the chest, further adding to the discomfort, and in many occasions preventing visualization of the skin area.

9. Previous attempts to solve the issue of drain fixation have involved a variety of taping solutions, additional sutures, and so on. All of these result in considerable discomfort for the child.

10. Claimed embodiments of Dr. Spinoza's invention offer a number of potential advantages in my view. For example, it will be a much simpler technique of insertion and fixation requiring very limited suturing for the child. The load on the drain is spread over a much wider area and the traction is not transferred with such vigor to the skin. It would be very quick to insert, which is an advantage in children and because of the cleverness of the design it would be relatively straightforward to re-position the tube, should that be required. Less adhesive tape to the skin will be required, visibility of the entry site will be improved, and it will be easier to care for the wound and thus reduce the likelihood of infection.

11. Chest drain displacement can be very dangerous in the presence of pneumothorax or major hemorrhage and so a well fixed, safe tube with easy access to its entry site could indeed save lives.

12. I have reviewed the "Shorey document," which is Patent Document GB 2,061,372 entitled, "Improvements in cable grips." I understand that the United States Patent Office has cited the Shorey document in conjunction with Dr. Spinoza's patent application.

13. The Shorey document discloses how to make a woven cable grip device, which according to columns 1 lines 8-10 "can be used to pull a cable into a required position or to support a cable in a desired position or both." This is not a technical area with which I am familiar, indeed I was not previously aware of the existence of any such devices.

14. I understand the United States Patent Office has considered medical tubes of Dr. Spinoza's invention and cable lines of the Shorey document and stated, "A tube is analogous in structure to a cable line. It would have been obvious to one of ordinary skill in the art to recognize that the cable line and the tube are interchangeable and can be used in medical arts as it relates with the tube." I do not agree with this assertion.

15. The devices disclosed in the Shorey document are designed to grip electrical cables and support the weight of those cables. I can see nothing in the Shorey document which suggests a medical or surgical fastener for securing a tube to a patient. Additionally, in my opinion, the devices in the Shorey document are of a construction that would make them entirely unsuitable for such use in the medical application at least because of their weight and strength, which would deform thin, flexible walls of medical tubing, resulting in impaired fluid flow or damage to tube walls.

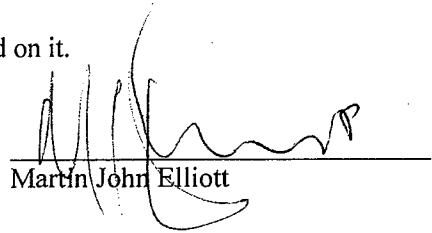
16. The Shorey document is not from the same field of endeavor as Dr. Spinoza's invention.

17. I do not believe that the Shorey document is pertinent to the problem addressed by the invention of Dr. Spinoza. Nor do I believe that the Shorey document would have logically commended itself to the attention of an inventor considering and attempting to solve the problem addressed by the invention of Dr. Spinoza.

18. I declare that all statements made of my own knowledge are true and all statements made on information are believed to be true and further that the statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under § 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of this application or any patent issued on it.

Date: _____

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Martin John Elliott